DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 17, 2014

Ardo Medical AG
% Yarmela Pavlovic
Regulatory Counsel
Hogan Lovells, LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K141742
Trade/Device Name: Ardo Carum and Calypso Powered Breast Pumps
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: Class II
Product Code: HGX
Dated: September 2, 2014
Received: September 2, 2014

Dear Yarmela Pavlovic,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K141742

Device Name

ARDO Carum and Calypso Powered Breast Pumps

Indications for Use *(Describe)*

The ARDO Carum powered breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for multiple users.

The ARDO Calypso breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for single users.

The ARDO Pumpset should be used in combination with ARDO breast pumps and is intended to be used by lactating women to express and collect milk from their breast. The Pumpset can be used both as a single pumpset and as a double pumpset.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA)
Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

ARDO'S CARUM AND CALYPSO POWERED BREAST PUMPS

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Ardo medical AG
Gewerbestrasse 19
6314 Unteraegeri
Switzerland
E-mail: info@ardo.ch
Phone: ++41 41 / 754 70 70
Facsimile: ++41 41 / 754 70 71
Contact Person: Roger Dubach

Date Prepared: October 9, 2014

Name of Device

CARUM and CALYPSO, POWERED BREAST PUMPS

Name/Address of Correspondent

Yarmela Pavlovic, Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103
Telephone +1 267 675 4600
FAX +1 267 675 4601
E-mail: yarmela.pavlovic@hoganlovells.com

Common or Usual Name

Powered breast pump

Classification Name

HGX, Powered breast pump
21 C.F.R. § 884.5160

Predicate Device

Medela Symphony Breast Pump Model 024 (K020518).

Device Description

ARDO Carum and Calypso Powered Breast Pumps consist of the breast milk pump and a pump set (single or double pump set). They are double piston or reciprocating pumps for hospital, rental and personal use. The units are equipped with a robust plastic housing and a simplified, logically-

organized keyboard with an LCD display readout.

The electrical equipment is designed for outlet and for car battery-operation, or for (optional) battery use. The controls allow each mother to customize the settings through a flexible system for adjusting vacuum and cycles. For both the Carum and Calypso breast pumps, the vacuum level remains stable when the user changes the cycle setting. Likewise, the cycle level remains stable when the user changes the vacuum setting. A non-sterile pump set is included for collection and storage of milk.

Three models of ARDO Powered Breast Pumps are available:

- Calypso with battery compartment and outlet adapter;
- Carum with outlet cord; and
- Carum with built in rechargeable battery and outlet cord.

Accessories for Carum include:

- Power cord;
- Protective carrying case;
- Car adapter (12VDC);
- Trolley;
- Bottle holder;
- EasyFreeze holder;
- EasyFreeze bag; and
- PumpSets.

Accessories for Calypso include:

- Power cord;
- Bottle holder;
- Nylon bags for accessories and for the PumpSet;
- EasyFreeze bag;
- Breastfeeding bag (Shoulder Bag consisting of cold bag, cooling elements, Calypso bag and Pumpset bag); and
- Pumpsets.

Intended Use / Indications for Use

The ARDO Carum powered breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for multiple users.

The ARDO Calypso breast pump is intended to be used by lactating women to express and collect milk from their breast. It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for single users.

The ARDO Pumpset should be used in combination with ARDO breast pumps and is intended to be used by lactating women to express and collect milk from their breast. The Pumpset can be used both as a single pumpset and as a double pumpset.

Technological Characteristics

The Carum and Calypso Powered Breast Pumps have similar technological characteristics compared to the predicate device. Each features a pump with suction connections and variable vacuum and cycle ranges. All devices provide a pump set with plastic bottles. Key differences between the devices include slight variation in the vacuum range, 30/50-330 mbar for the subject devices compared to 50-250 mbar for the predicate device. In addition, the range of cycles per minute differs slightly between the devices. These minor technological differences do not raise any new types of safety or effectiveness questions because the key questions of effective milk collection and user comfort are common to all devices. Further, differences in patient-contacting materials were evaluated in testing and device materials were demonstrated to be biocompatible for its intended use. Therefore, the Carum and Calypso Pumps present similar technological characteristics compared to the predicate device in support of substantial equivalence.

Performance Data

The following performance tests were conducted:

- Microbiological Tightness (ISO 11737-1:2006);
- Biocompatibility;
    - Cytotoxicity (ISO 10993-5:2009/(R)2014);
    - Irritation (ISO 10993-10:2010);
    - Sensitization (ISO 10993-10:2010);
    - Acute systemic toxicity (ISO 10993-11:2006/(R)2010);
- Electromagnetic Safety (IEC 60601-1-2:2007);
- Electrical Safety (IEC 60601-1:2005); and
- Battery Safety (IEC 62133:2003, EN 60068-2-27:2009, EN 60068-2-6:2008).

In addition, the software was verified and validated. Evaluation of the vacuum pressure over time was conducted to determine the maximum vacuum pressure during a simulated, 20-minute pumping session. In all instances, the ARDO Carum and Calypso Powered Breast Pumps functioned as intended.

Conclusions

Based upon the information above, the ARDO Carum and Calypso powered breast pumps perform as intended and in a manner that is substantially equivalent to the predicate device. The Carum and Calypso Powered Breast Pumps are substantially equivalent to the Medela Symphony Powered Breast Pump. The Carum and Calypso Powered Breast Pumps have the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Carum and Calypso Powered Breast Pumps and their predicate device raise no new issues of safety or effectiveness. The testing data support the safety profile and performance of the device and demonstrate that the devices perform as intended in the specified use conditions. Thus, the Carum and Calypso Powered Breast Pumps are substantially equivalent.